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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/681,061 Confirmation No. 7845
Applicant : Sievers et al.
Filed : October 7, 2003
TC/A.U. : 1616
Examiner : Not assigned
For : SUPERCRITICAL FLUID-ASSISTED NEBULIZATION AND BUBBLE DRYING
Docket No. : 45-99A
Customer No. : 23713

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450



INFORMATION DISCLOSURE STATEMENT

Sir:

This application is a divisional of U.S. Application Serial No. 09/591,213, filed June 9, 2000, U.S. Patent No. 6,630,121. In accordance with 37 C.F.R. 1.98(d), copies of references cited in that application are not submitted, but will be provided upon request. Copies of PTO Form 1449s submitted in U.S. Application Serial No. 09/591,213 are enclosed.

It is believed that no fee is due with the submission of this Information Disclosure Statement. If this is incorrect, however, please charge the required fee and the fee for any extension of time needed to Deposit Account No. 07-1969.

Respectfully submitted,

Susan K. Doughty
Susan K. Doughty
Reg. No. 43,595

GREENLEE, WINNER AND SULLIVAN, P.C.
5370 Manhattan Circle, Suite 201
Boulder, CO 80303
Telephone: (303) 499-8080
Facsimile: (303) 499-8089
E-mail: winner@greenwin.com

Attorney docket No. 45-99A
can: February 5, 2004



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ATTY DOCKET NO. 45-99A	SERIAL NO. 10/681,061	FILING DATE October 7, 2003
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U.S. PATENT DOCUMENTS

Exmr. Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate

FOREIGN PATENT DOCUMENTS

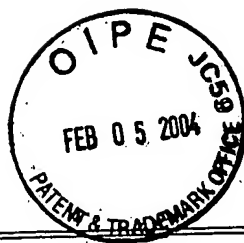
	Document Number	Date	Country	Class	Subclass	Translation Yes/No

OTHER PRIOR ART *(including Author, Title, Date, Pertinent Pages, etc.)*

		M. Adler et al., Stability and Surface Activity of Lactate Dehydrogenase in Spray-Dried Trehalose, J. Pharm. Sci. 88(2):199-208, 1999
		S. D. Allison et al., Effects of Drying Methods and Additives on Structure and Function of Actin: Mechanisms of Dehydration-Induced Damage and Its Inhibition, Arch. Biochem. Biophys. 358(1):171-181, 1998
		R. Sloan et al., Controlled Particle Formation of Biological Material Using Supercritical Fluids, presented at I.S.A.S.F. 6 th meeting on Supercritical Fluids - Chemistry and Materials, Nottingham, UK, pp. 169-175, April 10-13, 1999
		M. Winters et al., Precipitation of Proteins in Supercritical Carbon Dioxide, J. Pharm. Sci. 85(6):586-593, 1996

EXAMINER	DATE CONSIDERED
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

ORIGINALLY CITED IN 09/591,213



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Form PTO-1449		
ATTY DOCKET NO. 45-99A	SERIAL NO. 10/681,061	FILING DATE October 7, 2003
APPLICANT Sievers et al.		GROUP 1616

U.S. PATENT DOCUMENTS

Exmr. Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	6,165,463	12/26/00	Platz et al.	424	130.1	
	6,151,798	11/28/00	Petersen	34	304	
	6,136,346	10/24/00	Eijamai et al.	424	488	
	6,113,948	09/05/00	Heath et al.	424	499	
	6,103,270	08/15/00	Johnson et al.	424	489	
	6,095,134	08/01/00	Sievers et al.	128	200.14	
	6,080,762	06/27/00	Allen et al.	514	337	
	6,077,543	06/20/00	Gordon et al.	424	489	
	6,071,428	06/06/00	Aldous et al.	252	1	
	6,068,857	05/30/00	Weitchies et al.	424	489	
	6,063,910	05/16/00	Debenedetti et al.	530	418	
	6,063,138	05/16/00	Hanna et al.	23	295R	
	6,058,624	05/09/00	Bach et al.	34	374	
	6,056,791	05/02/00	Weidner et al.	23	295R	
	6,054,179	04/25/00	Combes et al.	427	212	
	6,051,256	04/18/00	Platz et al.	424	489	
	6,019,968	02/01/00	Platz et al.	424	130.1	
	6,001,336	12/14/99	Gordon	424	46	
	5,994,314	11/30/99	Eljamal et al.	514	44	
	5,993,805	11/30/99	Sutton et al.	424	94.1	
	5,993,783	11/30/99	Eljamal et al.	424	46	
	5,985,248	11/16/99	Gordon et al.	424	46	
	5,976,574	11/02/99	Gordon	424	489	
	5,955,108	09/21/99	Sutton et al.	424	489	
	5,928,469	07/27/99	Franks et al.	159	48.1	

ORIGINALLY CITED IN 09/591,213



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Form PTO-1449		
ATTY DOCKET NO. 45-99A	SERIAL NO. 10/681,061	FILING DATE October 7, 2003
APPLICANT Sievers et al.		GROUP 1616

		5,922,354	07/13/99	Johnson et al.	424	489	
		5,851,453	12/22/98	Hanna et al.	264	5	
		5,795,594	08/18/98	York et al.	424	489	
		5,725,987	03/10/98	Combes et al.	430	137	
		5,720,938	02/24/98	Schutt et al.	424	9.51	
		5,695,741	12/09/97	Schutt et al.	424	9.52	
		5,695,701	12/09/97	Funder et al.	264	117	
		5,654,007	08/05/97	Johnson et al.	424	489	
		5,647,142	07/15/97	Andersen et al.	34	373	
		5,639,443	06/17/97	Schutt et al.	424	9.52	
		5,639,441	06/17/97	Sievers et al.	424	9.3	
		5,531,219	07/02/96	Rosenberg	128	203/12	
		5,357,686	10/25/94	Jensen	34	169	
		5,100,509	03/31/92	Pisecky et al.	159	4.2	
		5,098,893	03/24/92	Franks et al.	514	54	
		4,734,451	03/29/88	Smith	524	493	
		4,734,227	03/29/88	Smith	264	13	
		4,582,731	04/15/86	Smith	427	421	
		4,070,765	01/31/78	Hovmand et al.	34	371	

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes/No
		960 651 A2	12/01/99	EP	B01F 7/18		
		820 415 B1	11/03/99	EP	B65D 83/14		
		767 702 B1	12/16/98	EP	B01J 2/04	A61K 9/16	
		706 421 B1	12/16/98	EP	B01J 2/04	B05B 7/06	
		383,569 B1	05/18/94	EP	C12N 9/96	C12N 11/00	

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Form PTO-1449		
ATTY DOCKET NO. 45-99A	SERIAL NO. 10/681,061	FILING DATE October 7, 2003
APPLICANT Sievers et al.		GROUP 1616

		370 268	05/30/90	EP	B29C 33/60		
		GB 2,334,900 A	09/08/99	UK	B01J 2/04	B01D 1/18	
		GB 2,322,326 A	08/26/98	UK	B01J 2/04	A61K 9/16	
		WO 00/61178	10/19/00	PCT	A61K 38/28	A61P 5/06	
		WO 00/15262	03/23/00	PCT	A61K 47/36		
		WO 00/10541	03/02/00	PCT	A61K 9/72	A61K 9/14	
		WO 00/00215	01/06/00	PCT	A61K 39/00		
		WO 99/66903	12/29/99	PCT	A61K 9/12		
		WO 99/59710	11/25/99	PCT	B01J 2/04	A61K 9/16	
		WO 99/44733	09/10/99	PCT	B01J 2/04	A61K 9/16	
		WO 99/19215	04/22/99	PCT	B65B 1/36		
		WO 99/16422	04/08/99	PCT	A61K 9/00		
		WO 99/16421	04/08/99	PCT	A61K 9/51		
		WO 99/16420	04/08/99	PCT	A61K 9/00		
		WO 99/16419	04/08/99	PCT	A61K 9/00		
		WO 98/58722	12/30/98	PCT	B01D 11/04	B01J 2/02	
		WO 98/36825	08/27/98	PCT	B01J 2/04	A61K 9/16	
		WO 98/29141	07/09/98	PCT	A61L 9/04		
		WO 98/29140	07/09/98	PCT	A61L 9/04		
		WO 98/29098	07/09/98	PCT	A61K 9/14	B29B 9/00	
		WO 98/29096	07/09/98	PCT	A61K 9/12		
		WO 98/17676	04/30/98	PCT	C07J 31/00	A61K 31/56	
		WO 97/41833	11/13/97	PCT	A61K 9/12		
		WO 97/41031	11/06/97	PCT	B65B 1/04	B67C 3/00	
		WO 96/32149	10/17/96	PCT	A61M 11/00		
		WO 96/00610	01/11/96	PCT	B01J 2/04	A61K 9/16	
		WO 95/01324	01/12/95	PCT	C07C 215/60		



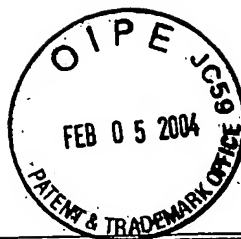
Form PTO-1449		
ATTY DOCKET NO. 45-99A	SERIAL NO. 10/681,061	FILING DATE October 7, 2003
APPLICANT Sievers et al.		GROUP 1616

		WO 95/01221	01/12/95	PCT	B01J 2/04	B05B 7/06	

OTHER PRIOR ART (including Author, Title, Date, Pertinent Pages, etc.)

		Adler, M. and Lee, G. (1999), "Stability and Surface Activity of Lactate Dehydrogenase in Spray-Dried Trehalose," J. Pharm. Sci. 88:199-208
		Allison, D.S. et al. (1998), "Effects of Drying Methods and Additives on Structure and Function of Actin: Mechanisms of Dehydration-Induced Damage and Its Inhibition," Arch. Biochem. Biophys. 358:171-181
		Beach, S. et al. (1999), "Control of the Physical Form of Salmeterol Xinafoate," Org. Proc. Res. Dev. 3:370-376
		Carpenter, J.F. et al. (1998), "Application of Infrared Spectroscopy to Development of Stable Lyophilized Protein Formulations," Eur. J. Pharm. Biopharm. 45:231-238
		Chang, B.S. et al. (1996), "Physical Factors Affecting the Storage Stability of Freeze-Dried Interleukin-1 Receptor Antagonist: Glass Transition and Protein Conformation," Arch. Biochem. Biophys. 331:249-258
		Crowe, J.H. et al. (1998), "The Role of Vitricification in Anhydrobiosis," Annu. Rev. Physiol. 60:73-103
		Dagani, R. (2000), "Better, Cheaper 'Green' Solvent," Chem. Eng. News, p. 11.
		Domingo, C. et al. (1997), "Precipitation of ultrafine organic crystals from the rapid expansion of supercritical solutions over a capillary and a frit nozzle," J. Supercritical Fluids 10:39-55
		Dong, A. et al. (1990), "Protein secondary structures in water from second-derivative amide I infrared spectra," Biochem. 29:3303-3308
		Dong, A. and Caughey, W.S. (1994), "Infrared methods for study of hemoglobin reactions and structures," Methods Enzymol. 232:139-175
		Dong, A. et al. (1995), "Infrared Spectroscopic Studies of Lyophilization- and Temperature-Induced Protein Aggregation," J. Pharm. Sci. 84:415-424
		Forbes, R.T. et al. (1998), "Production of Stable Protein Particles: A Comparison of Freeze, Spray and Supercritical Drying," presented at the World Congress on Particle Technology 3, Brighton, UK (7-9 July 1998), 8 pp.
		Giessauf, A. and Gamse, T. (2000), "A simple process for increasing the specific activity of porcine pancreatic lipase by supercritical carbon dioxide treatment," J. Mol. Catal. B: Enzymatic 9:57-64

ORIGINALLY CITED IN 09/591,213



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Form PTO-1449		
ATTY DOCKET NO. 45-99A	SERIAL NO. 10/681,061	FILING DATE October 7, 2003
APPLICANT Sievers et al.		GROUP 1616

		Hybertson, B.M. (1993), "Pulmonary Drug Delivery of Fine Aerosol Particles from Supercritical Fluids," <i>J. Aerosol Medicine: Deposition, Clearance and Effects in the Lung</i> , 6,4: 275-285
		Kamihira, M. et al. (1987), "Sterilization of Microorganisms with Supercritical Carbon Dioxide," <i>Biol. Chem.</i> 51(2):407-412
		Lai, M.C. and Topp, E.M. (1999), "Solid-State Chemical Stability of Proteins and Peptides," <i>J. Pharm. Sci.</i> 88:489-500
		Larson, K.A. and King, M.L. (1986), "Evaluation of Supercritical Fluid Extraction in the Pharmaceutical Industry," <i>Biotechnol. Prog.</i> 2:73-82
		Manning, M.C. et al. (1989), "Stability of Protein Pharmaceuticals," <i>Pharm. Res.</i> 6:903-918
		Meyer, J.D. et al. (1998), "Preparation and in vitro characterization of gentamycin-impregnated biodegradable beads suitable for treatment of osteomyelitis," <i>J. Pharm. Sci.</i> 87:1149-1154
		Mohamed, R.S. et al. (1988), "Solids Formation After the Expansion of Supercritical Mixtures," in <i>Supercritical Fluid Science and Technology</i> , Johnston, D.P. et al. (eds.), Am. Inst. of Chem. Eng. Annual Meeting, Washington, DC, November 27 - December 2, 1988, pp. 357-378
		Palakodaty, S. and York, P. (1999), "Phase Behavioral Effect on Particle Formation Processes Using Supercritical Fluids," <i>Pharm. Res.</i> 16(7):976-985
		Palakodaty, S. et al. (1998), "Supercritical fluid processing of materials from aqueous solutions: the application of SEDS to lactose as a model substance," <i>Pharm. Res.</i> 15:1835-1843
		Prestrelski, S.J. et al. (1993), "Dehydration-induced Conformational Transitions in Proteins and Their Inhibition by Stabilizers," <i>Biophys. J.</i> 65:661-671
		Randolph, T.W. et al. (1993), "Sub-micrometer-sized biodegradable particles of poly(L-lactic acid) via the gas antisolvent spray precipitation process," <i>Biotechnol. Prog.</i> 9:429-435
		Reverchon, E. (1999), "Supercritical antisolvent precipitation of micro- and nano-particles," <i>J. Supercritical Fluids</i> 15:1-21
		Reverchon, E. et al. (1995), "Solubility and Micronization of Griseofulvin in Supercritical CHF ₃ ," <i>Ind. Eng. Chem. Res.</i> 34:4087-4091
		Sarbu, T. et al. (2000), "Non-fluorous polymers with very high solubility in supercritical CO ₂ down to low pressures," <i>Nature</i> 405:154-168

ORIGINALLY CITED IN 09/591,213



Sheet 6 of 7

Form PTO-1449		
ATTY DOCKET NO. 45-99A	SERIAL NO. 10/681,061	FILING DATE October 7, 2003
APPLICANT Sievers et al.		GROUP 1616

		Shekunov, B. Yu. Et al. (2000), "Optical Characterisation and Mechanism of Antisolvent Precipitation in Turbulent Flow," Proc. of the 7 th Meeting on Supercritical Fluids, Particules Design, Materials and Natural Products Processing, Tome 1, Antibes/Juan-Les-Pins, France, December 6,7,8, 2000, pp. 65-70
		Shekunov, B. Yu. Et al. (2000), "Precipitation of Acetaminophen and P-acetoxycetanilide in Supercritical CO ₂ ," Proc. of the 7 th Meeting on Supercritical Fluids, Particules Design, Materials and Natural Products Processing, Tome 1, Antibes/Juan-Les-Pins, France, December 6,7,8, 2000, pp. 111-116
		Shekunov, B. Yu. et al. (1999), "Crystallization process in turbulent supercritical flows," J. Cryst. Growth 198/199:1345-1351
		Shishikura, A. et al. (1994), "Separation and Purification of Organic Acids by Gas Antisolvent Crystallization," J. Agric. Food Chem. 42:1993-1997
		Sievers, R.E. et al. (1999), "Formation of Aqueous Small Droplet Aerosols Assisted by Supercritical Carbon Dioxide," Aerosol Sci Technol. 30:3-15
		Sloan, R. et al. (1999), "Controlled Particle Formation of Biological Material Using Supercritical Fluids," presented at I.S.A.S.F. 6 th Meeting on Supercritical Fluids - Chemistry and Materials (10-13 April 1999), Nottingham, UK (Proc. ISBN 2-905-267-30-5), 6 pp.
		St. John, R.J. et al. (1999), "High Pressure Fosters Protein Refolding from Aggregates at High Concentrations," Proc. Natl. Acad. Sci. 96:13029-13033
		Tom, J.W. and Debenedetti, P.G. (1991), "Formation of Bioerodible Polymeric Microspheres and Microparticles by Rapid Expansion of Supercritical Solutions," Biotechnol. Prog. 7:403-411
		Winters, M.A. et al. (1996), "Precipitation of proteins in supercritical carbon dioxide," J. Pharm. Sci. 85:586-594
		York, P. (1999), "Strategies for particle design using supercritical fluid technologies," PSTT 2(11):430-440

EXAMINER	DATE CONSIDERED
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

12/20/89

ORIGINALLY CITED IN 09/591,213



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APPLICANT: Sievers et al.		GROUP: 1616

U.S. PATENT DOCUMENTS

Exmr. Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	5,864,923	02/02/99	Rouanet et al.	23	295 R	
	5,770,559	06/23/98	Manning et al.	514	2	
	5,707,634	01/13/98	Schmitt	424	400	
	5,301,664	04/12/94	Sievers et al.	128	200.23	
	5,266,205	11/30/93	Fulton et al.	210	639	
	4,970,093	11/13/90	Sievers et al.	427	38	
	4,845,056	07/04/89	Yamanis	501	12	

FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation Yes/No
0 906 951 A3	04/07/99	EP	C12N 1/04		
0 906 951 A2	05/19/99	EP	C12N 1/04		
0 711 586 B1	08/23/00	EP	B01D 1/18		
0 667 322	08/16/95	EP	C04B 35/00		
WO 95/21688	08/17/95	PCT	B01J 2/00		
WO 95/03106	02/02/95	PCT	B01D 15/08		

OTHER PRIOR ART (including Author, Title, Date, Pertinent Pages, etc.)

	Edwards et al., (1998), "Recent advances in pulmonary drug delivery using large, porous inhaled particles," J. Appl. Physiol. 85:379-385
	Hansen et al., (1992), "Supercritical Fluid Transport - Chemical Deposition of Films," Chem. Mater. 4:749-752
	Johnson et al., (1996), "Electrostatic-Enhanced Atomization for Spray Drying of Milk," J. Lebensm.-wiss 4.-Technol. 29:71-81

ORIGINALLY CITED IN 09/591,213



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Form PTO-1449		
ATTY DOCKET NO. 45-99A	SERIAL NO. 10/681,061	FILING DATE: October 7, 2003
APPLICANT: Sievers et al.		GROUP: 1616

			<i>Sarbu et al., (May 2000), "Non-fluorous polymers with very high solubility in supercritical CO₂ down to low pressures," Nature 405:165-168</i>
			<i>Sato et al., (1984), "The Production of Essentially Uniform-Sized Liquid Droplets in Gaseous or Immiscible Liquid Media Under Applied A.C. Potential," J. Electrostatics 15:237-247</i>
			<i>Sievers et al., (1996), "Supercritical CO₂-Assisted Nebulization for the Production and Administration of Drugs," J. Aerosol. Sci. 27:S497-S498</i>
			<i>Sievers et al., (1998), "Supercritical CO₂-assisted methods for the production and pulmonary administration of pharmaceutical aerosols," J. Aerosol Sci. 29:S1271-S1272</i>
			<i>Winters et al. (Feb 1999), "Protein Purification with Vapor-Phase Carbon Dioxide," Biotechnol. Bioeng. 62(3):247-258</i>
			<i>Xu, C.Y. et al., (1998), "Supercritical carbon dioxide assisted aerosolization for this film deposition, fine powder generation, and drug delivery," Green Chemistry: Frontiers in Benign Chemical Synthesis and Processing, Oxford Press, Oxford pp. 312-335</i>

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

12/20/89



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APPLICANT Sievers et al.		GROUP 1616

U.S. PATENT DOCUMENTS

Exmr Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	1	6,197,836	3/6/01	Riede et al.	516	31	
	2	20010000036	3/15/01	Riede et al	516	31	11/30/00

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes/No

OTHER PRIOR ART (including Author, Title, Date, Pertinent Pages, etc.)

EXAMINER	DATE CONSIDERED
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Exmr. Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate

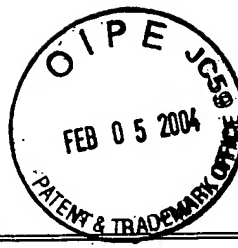
FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes/No

OTHER PRIOR ART *(including Author, Title, Date, Pertinent Pages, etc.)*

			Edwards, AD. et al., "The Structure and Morphology of Poly (L-Lactide) Particles Formed By Spray Drying and Solution Enhanced Dispersion By Supercritical Fluids (SEDS)" (April 1999) Proceedings of the 18 th Pharmaceutical Technology Conference, Vol. 1, pp 37-44
EXAMINER		DATE CONSIDERED	
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>			

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APPLICANT Sievers et al.		GROUP 1616

U.S. PATENT DOCUMENTS

Exmr Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	1	5,833,891	11/10/98	Subramaniam et al.	264	7	

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes/No

OTHER PRIOR ART (including Author, Title, Date, Pertinent Pages, etc.)

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